What factors influence the continuity of care following completion of a clinical trial? A qualitative study of patient experiences

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Introduction

Research activity has grown over the preceding 10 years and is now embedded as core NHS business. As a result more NHS patients are becoming research participants. The ethical and regulatory requirements of conducting clinical research ensure the rights and safety of study participants are maintained during trial participation (ICH 2016). However, there is currently no statutory requirement for, or guidance on, the provision of ongoing care once the trial has completed. This is an often overlooked area of nursing practice. This study explored the lived experience of clinical trial participation, conclusion and provision of ongoing care from the patient's perspective.

Methods

Seven participants who had completed a clinical trial in the last year at the same hospital Trust were purposively selected. Data were collected via semi-structured, in-depth interviews between July and October 2016. Interviews were recorded and transcribed verbatim. Interpretative phenomenological analysis (IPA) (Smith *et al* 2009) was used to develop themes and interpret the findings.

Participant	Age	Sex	Disease group	Type of clinical trial
P01	69	Male	Cardiology & Urology	Medical device & Surgical intervention
P02	30	Female	Dermatology	Phase III placebo controlled drug trial
P03	51	Male	Dermatology	Phase III randomised controlled trial
P04	73	Male	Cardiology	Phase IV placebo controlled drug trial
P05	39	Female	Maternity	Intervention
P06	30	Female	Lupus	Phase III randomised controlled drug trial
P07	58	Female	Renal (transplant)	Phase IV randomised controlled drug trial

Table 1 Participant Details

References

International Conference on Harmonisation (ICH) (2016) Good Clinical Practice Guidelines E6 (R2) ICH

Smith J. A., Flowers P. & Larkin M. (2009) Interpretative Phenomenological Analysis. Theory, Method and Research. Sage, London.

Results

Three super-ordinate themes were identified during the data analysis. These were broken down into their constituent sub-themes as displayed in Figure 1. In keeping with IPA, the themes were analysed and interpreted using direct quotations from the participant interviews.

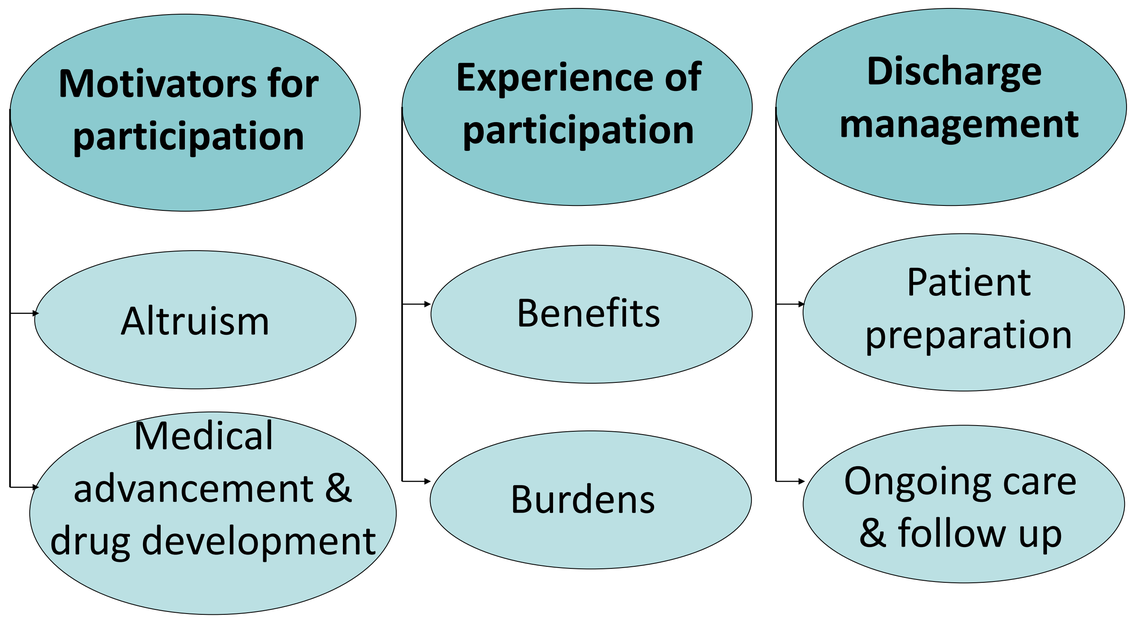

Figure 1 Summary of Super-ordinate themes and sub-themes

Main findings

- Access to novel treatments and intensive monitoring were reported benefits of participation developing trust in the clinical team.
- Some felt underprepared for trial completion due to a fear of losing the close relationship established with their research team.
- Enhanced communication between research and ongoing clinical team, provision of ongoing care at study withdrawal and maintained contact with the research nurse after completion improved post trial experiences.

literally I just felt like at that appointment it was like, you know, yeah, bye bye, we've got the information we need and then gone (P06).

…..it was wonderful that I still had her (research nurse) phone number it was like a lifeline really, I would hate to be without that (P01).

it was really good they (research team) made sure that I knew what was going on and what was going to happen to me because I couldn't be in the study anymore so they told me where to go and what would happen so it was quite informative. I wasn't worried at all (P02).

Conclusions and recommendations

- Follow-up after trial completion is essential to ensure the safety and wellbeing of study participants and shows respect for their important contribution to the development of medical interventions.
- Integration of research nursing practice within clinical care will improve communication and continuity of care for study participants following trial completion.
- Further research examining strategies to embed a research nursing culture within existing clinical care environments are recommended.